Journal of Pain Research

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EXPERT OPINION

The American Society of Pain and Neuroscience (ASPN) Guidelines for Radiofrequency Ablative Procedures in Patients with Implanted Devices

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Abstract: Radiofrequency ablation (RFA) is a treatment modality used in interventional pain management to treat several conditions including chronic neck or back pain, sacroiliac joint pain, major joint pain, and pain from sites that can be isolated to a sensory nerve amenable to RFA. The goals of such procedures are to reduce pain, improve function, delay need for surgical intervention, and reduce pain medication consumption. As applications for RFA expand through novel techniques and nerve targets, there is concern with how RFA may impact patients with implanted medical devices. Specifically, the electrical currents used in RFA produce electromagnetic interference, which can result in unintentional energy transfer to implanted devices. This may also interfere with device function or cause damage to the device itself. As the number of patients with implanted devices increases, it is imperative to establish guidelines for the management of implanted devices during RFA procedures. This review aims to establish guidelines to assist physicians in the preoperative, intraoperative, and postoperative management of implanted devices in patients undergoing procedures using radiofrequency energy. Here, we provide physicians with background knowledge and a summary of current evidence to allow safe utilization of RFA treatment in patients with implanted devices such as cardiac implantable electronic devices, spinal cord stimulators, intrathecal pumps, and deep brain stimulators. While these guidelines are intended to be comprehensive, each patient should be assessed on an individual basis to optimize outcomes.

Keywords: radiofrequency ablation, implanted medical devices, cardiac implantable electronic device, spinal cord stimulator, intrathecal pump, deep brain stimulator

Introduction

Radiofrequency Ablation

Radiofrequency ablation (RFA) is a treatment modality used in multiple specialties from treatment of cardiac arrhythmias to targeted destruction of tumors. It is used in interventional pain management to treat several conditions including chronic neck or back pain, sacroiliac joint pain, major joint pain, and pain from sites that can be isolated to a sensory nerve amenable to RFA. Conventional or thermal RFA uses a needle that delivers continuous high-voltage current to produce a heat lesion on a pain-transmitting nerve. The tip of the needle is heated to approximately 80 degrees Celsius, and the resulting lesion disrupts the pain signals to the brain. Pulsed radiofrequency utilizes short bursts of high-voltage current with intermittent pauses resulting in lower temperatures of approximately 42 degrees Celsius. The proposed mechanism of action is thought to be modulation of pain signals rather than thermal destruction of the nerve. The goals of such procedures are to reduce pain, improve function, delay or eliminate the need for surgical intervention, and reduce

Received: 2 May 2023
Accepted: 26 October 2023
Published: 3 November 2023

pain medication requirements. Contraindications to RFA are few but include site specific use of anticoagulants, site infection, and the inability of the patient to consent or desire not to proceed with the procedure. The electrical currents used in RFA produce electromagnetic interference (EMI) which can rarely result in unintentional energy transfer to implanted devices. This could theoretically interfere with device function or damage the device. As a result of this potential interference and the growing number of implanted devices, it is imperative to establish guidelines for the management of these devices during RFA procedures.

Problem

Implanted devices are becoming more prevalent as technologies improve and average lifespan continues to grow. Applications for RFA are also expanding with novel techniques and nerve targets. This increases the potential use of RFA in patients with implanted devices.

Goal

The primary objective of this review is to update previous recommendations and provide current guidelines to assist physicians and affiliated healthcare professionals in the preoperative, intraoperative, and postoperative management of implanted devices in patients undergoing procedures using radiofrequency energy.[1–3] In addition, we hope to shape procedures and policies of institutions to improve patient safety in this population.

Application of Guidelines

These guidelines aim to provide physicians with background knowledge and a summary of current evidence to allow safe utilization of RFA treatment in patients with implanted devices. While these guidelines are intended to be comprehensive, each patient should be assessed on an individual basis to optimize outcomes.

Methods

We have prepared a clinical guideline on management of implanted devices in patients undergoing RFA procedures. Data sources included relevant literature identified through searches of PubMed as well as manufacturer-provided information. Bibliographies of included primary and review articles were also searched for additional relevant literature. Search terms included relevant key words and phrases such as radiofrequency ablation, electromagnetic interference, cardiac implantable electronic devices, pacemaker, deep brain stimulator, spinal cord stimulator, and intrathecal pump. Guidelines were then developed by a multidisciplinary physician group with input from experts in the fields of electrophysiology, interventional pain management, and neurosurgery.

Quality Assessment, Evidence Ranking, and Level of Certainty

Identified peer-reviewed literature was critiqued using the United States Preventive Services Task Force (USPSTF) criteria for quality of evidence, with modifications for neuromodulation studies (Table 1).[4] After USPSTF letter grading was assigned, the panel then assigned the "level of certainty regarding benefit" as described in Table 2.

Results

Cardiac Implantable Electronic Devices

Background

Cardiac implantable electronic devices (CIEDs) include pacemakers, implanted cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy devices (CRTDs). Each of these devices have specific functions which need to be clearly identified and managed. Pacemakers are used to manage cardiac arrhythmias and conduction abnormalities. In heart failure patients, ICDs provide immediate shock therapy when non-perfusing tachyarrhythmias are detected, and CRTDs provide pacing for dyssynchronous ventricular activation to optimize cardiac output.[5] CIEDs are becoming more common as technological advances have broadened indications. Increased device complexity makes it even more important that providers have adequate knowledge to manage these devices.

Table 1 Quality of Evidence Ranking Using United States Preventative Services Task Force Criteria Modified for Neuromodulation

Grade	Definition	Suggestions for PRACTICE
A	ASPN recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	ASPN recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	ASPN recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	ASPN recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	ASPN concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Table 2 Levels of Certainty Regarding Net Benefit

Level of Certainty	Description
High	The available evidence includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcome

Components

CIEDs are comprised of a pulse generator attached to electrodes or leads. The pulse generator is typically implanted in the infraclavicular region of the anterior chest wall and connected to transvenously placed leads anchored in the myocardium. The electrodes may function in sensing, pacing, defibrillating, or some combination depending on the device type. Sensing electrodes detect both intrinsic and extrinsic electrical currents. Output is then delivered in the form of pacing or defibrillation based on input from the sensing electrode.[5]

Effect of EMI on CIEDs

EMI from an extrinsic source, including RFA treatments, may be sensed and trigger a response. In pacemakers, sensed electrical current will inhibit the device from delivering additional current to avoid cardiac dyssynchrony and "R on T" phenomenon. Inhibition of therapy can result in asystole in a pacemaker-dependent patient. In ICDs, sensed electrical current may be interpreted as a non-perfusing tachyarrhythmia which will elicit delivery of cardioversion therapy. Less common problems that may be caused by EMI are device reset, pulse generator damage, and lead-tissue interface damage. To avoid interference, some manufacturers recommend a minimum distance of 15cm between sources of EMI and CIEDs.[6] Manufacturer recommendations should be confirmed for each device. In anatomical terms, EMI below the umbilicus (correlates with L3–4) is unlikely to cause significant interference.

Preoperative Evaluation

Preoperative evaluation lays the foundation for safe intra- and post-operative outcomes. Management should be individualized to each patient based on the device and planned procedure. Information that should be obtained includes device type (including manufacturer and model), indication, most recent device interrogation, pacemaker dependency, programming, and response to magnet placement. This information may be obtained by patient history, review of records, manufacturer ID card, or requested from the managing CIED team. Direct communication and planning with the CIED team should be considered in high-risk patients (above the umbilicus, presence of both ICD and PPM, pacemaker dependency, etc) or if there are any questions regarding device management. Ideally, device interrogation should be performed within the last six months for ICDs and 12 months for pacemakers.[7] A physical exam should be considered in high-risk patients to assess IPG location. This will help determine the distance from the planned RFA and identify any potential issues with magnet placement.

Preoperative Management

If EMI is located below the umbilicus, no changes to the device are needed. If EMI is going to be located above the umbilicus, recommendations from the managing CIED team should be obtained or the following algorithm should be considered (Figure 1). In general, magnet placement alters pacemaker function to asynchronous mode or suspends the

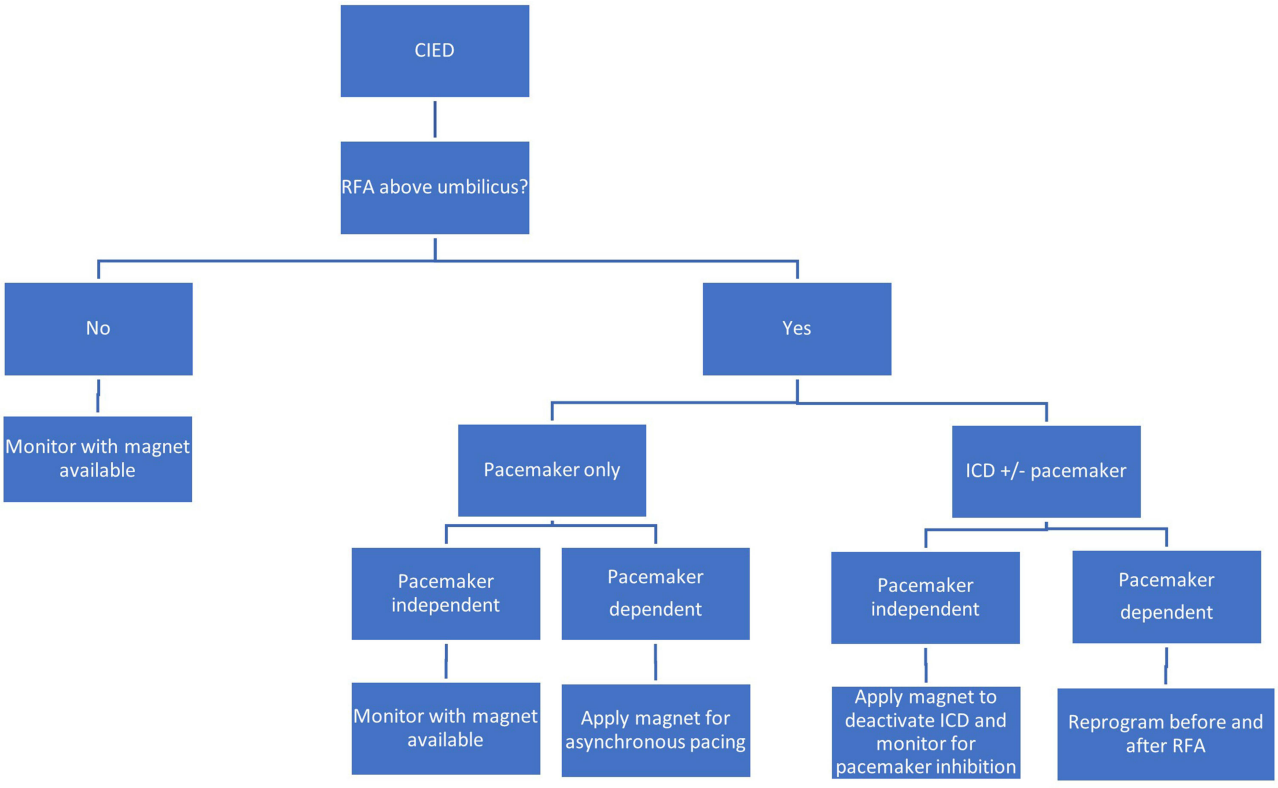

Figure 1 CIED Management Algorithm.

anti-tachycardia function of the ICD. In patients with combined ICD-PPM, a magnet will only suspend the anti-tachycardia function of the ICD without affecting the function of the pacemaker. If the patient is pacemaker-dependent and/or has an ICD, the device must be managed with either placement of a magnet or reprogramming of the device. Placing a magnet is sufficient in pacemaker-dependent patients without an ICD and in non-pacemaker-dependent patients with an ICD. If the patient has an ICD and is also pacemaker-dependent, the device will need to be reprogrammed as a magnet will only disable anti-tachycardia function without providing asynchronous pacing. Positioning may present a challenge for management of CIEDs as patients are often in the prone position for applications of RFA in interventional pain. If the magnet will be difficult to keep in place over the generator due to body habitus, chest roll, operating table configuration, or any other reason, consider contacting the device representative to reprogram the device prior to positioning. If using a magnet at any time during surgery, the magnet must remain in place the entire time. Once the magnet is removed, the CIED reverts to its baseline settings.[5]

Intraoperative Management

Patients should be monitored with standard ASA monitors including ECG (in pacing mode, if available), blood pressure, ETCO2, and pulse oximetry with plethysmography. A magnet as well as transcutaneous pacing and defibrillation pads should be available for all patients. Care should be taken to place the cautery pad away from the CIED in a manner to direct the EMI path away from the CIED. This may be achieved using bipolar RFA, which has been used safely in patients with CIEDs.[8] Time of EMI exposure should be limited to the minimal amount needed to achieve the desired clinical outcome.[9]

Postoperative Management

Postoperatively, patients with a CIED should have continuous cardiac rate monitoring until device settings are restored. Back-up pacing and cardioversion-defibrillation equipment should remain immediately available.[10] If a magnet was used, programmed settings typically resume with magnet removal. If the device was reprogrammed for the procedure, preprocedural settings will need to be restored by a device representative or CIED team member. An immediate post-operative interrogation of a CIED may not be required but should be considered if RFA occurred above the umbilicus. CIED interrogation should be performed if:

1. CIED was reprogrammed pre- or intraoperatively.
2. Significant intraoperative events occurred including arrhythmias requiring transcutaneous pacing, delivery of anti-tachycardia therapy (by CIED or external pads), cardiac arrest, etc.
3. There was concern for CIED malfunction.[9,10]

Recommendations: Application of guidelines and risk mitigation strategies in patients with CIEDs undergoing RFA will likely improve patient safety and adverse events. Evidence is limited to case reports and additional high-quality studies are needed. Grade B, moderate level of certainty (Table 3).

Spinal Cord Stimulators

Background

Spinal cord stimulators (SCS) have been used for chronic pain treatment since 1967.[15,16] The mechanism of action is explained mostly by Gate Control Theory, which proposes that non-painful stimuli "close" the gate, prevent transmission of painful afferent signals via wide-dynamic range neurons to the brain, and attenuate perception of pain.[16] Other subsequent theories proposed include dorsal horn GABAergic inhibitory interneurons, supraspinal involvement, and vasculature involvement in ischemic pain. SCS devices are typically utilized in the setting of chronic axial or appendicular neuropathic pain, radicular pain, complex regional pain syndrome (CRPS), and failed back surgery syndrome, all of which are approved indications by the Food and Drug Administration (FDA).[17] Additional indications exist including chronic intractable angina, peripheral vascular disease, postherpetic neuralgia, central pain from multiple sclerosis (MS), visceral pain, and painful spasms of atypical stiff limb syndrome.

Table 3 CIED Manufacturer Recommendations*

Abbott[11,12]	Radiofrequency ablation (RFA) in patients with a device may cause any of the following: asynchronous pacing above or below the programmed rate; reversion to an asynchronous operation; device electrical reset; premature triggering of the elective replacement indicator; or device malfunction or damage. Minimize RFA risks by doing the following: • Programming all tachyarrhythmia therapies off • Program a non-rate-responsive, asynchronous pacing mode prior to the RFA procedure. • Avoid direct contact between the ablation catheter and the implanted lead or pulse generator. • Position the ground plate so that the current pathway does not pass near the pulse generator system; in other words, place the ground plate under the patient's buttocks or legs. • Always have a separate standby external defibrillator immediately available. • Have a programmer available
Boston Scientific[13]	Electrocautery and RFA may induce ventricular arrhythmias and/or fibrillation, and may cause asynchronous pacing, inhibition of pacing, and/or a reduction in pulse generator pacing output possibly leading to loss of capture. RFA may also cause ventricular pacing up to the MTR and/or changes in pacing thresholds. Additionally, exercise caution when performing any other type of cardiac ablation procedure in patients with implanted devices. If electrocautery or RFA is medically necessary, observe the following to minimize risk to the patient and device: • Depending on the pacing needs of the patient, enable the Electrocautery Protection Mode, program to an asynchronous pacing mode, or use a magnet to switch to asynchronous pacing. An option for patients with intrinsic rhythm is to program the Brady Mode to VVI to the rate below the intrinsic rate to avoid competitive pacing. • Have temporary pacing and external defibrillation equipment available. • Avoid direct contact between the electrocautery equipment or ablation catheters and the pulse generator and leads. RFA close to the lead electrode may damage the lead-tissue interface. • Keep the path of the electrical current as far away as possible from the pulse generator and leads. • If RFA and/or electrocautery is performed on tissue near the device or leads, monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity and stability of the system. • For electrocautery, use a bipolar electrocautery system where possible and use short, intermittent, and irregular bursts at the lowest feasible energy levels. • RFA equipment may cause telemetry interference between the pulse generator and PRM. If device programming changes are necessary during an RFA procedure, turn off the RFA equipment before interrogation. When the procedure is finished, cancel the Electrocautery Protection Mode in order to reactivate the previously programmed therapy modes.
Medtronic[14]	Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction. Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions: • Ensure that temporary pacing and defibrillation equipment is available. • Avoid direct contact between the ablation catheter and the implanted system. • Position the return electrode patch so that the electrical current pathway does not pass through or near the device and lead system. • Always monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection. To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by implementing one of the following precautions: • Initiate the magnet mode (asynchronous pacing) by placing a magnet over the device. • Program the device to an asynchronous pacing mode (for example, DOO). After the ablation procedure, remove the magnet or restore device parameters.

Notes: *Manufacturer guidelines included for reference, but list is not comprehensive and confirmation of device specific recommendations is recommended.

Components

Traditional SCS devices use an array of electrodes that are implanted in the epidural space targeting the dorsal columns, specifically stimulating the A-beta fibers. The electrode at its distal portion is placed over the dorsal column. The

proximal segment is connected to an internal pulse generator (IPG), which administers energy to the electrodes.[18] It should be noted that this device is only permanently implanted following a successful lead trial with more than 50% pain reduction in addition to patient-reported satisfaction.[18]

Implantation of permanent SCS leads can be performed either via an interlaminar approach or laminectomy (typically when paddle leads are utilized). For the interlaminar approach, the entry point is several levels below the targeted spinal level for lead placement. Anchoring of the leads occurs at the point of epidural access. If using a laminectomy to place a paddle lead, the lead would be anchored directly over or very close to the intended paddle site. Proximal ends of the leads are tunneled beneath the skin and connected to the IPG, which is located subcutaneously, often in the flank or abdomen.[18]

Effect of EMI on Spinal Cord Stimulators

During use of a monopolar RFA needle, current travels through the patient and arrives to the ground electrode/panel, which is typically placed on the contralateral side of the patient's body. Increased risk of damage or injury may occur if the RFA needle is near enough to the IPG, SCS lead, or any tissue near the leads.[17] In contrast, it has been reported that use of a bipolar RFA needle, which uses one active electrode and one ground electrode with a shorter inter-distance, has decreased risk since it provides the opportunity for precise and predictive ablation of the target.[19]

Preoperative Evaluation and Management

The first task in preoperative evaluation of patients with implanted SCS devices is to determine the location of the device and any specific neurostimulator recommendations regarding EMI. Some devices have a surgery mode. Others do not, and the device needs to simply be turned off. Clinicians should also understand the difference between an implantable device being set in the "off" versus "surgery" mode. In certain devices, surgery mode creates greater protection of the IPG by releasing a small amount of electrical current to protect the lead from becoming a ground for the RFA. Informed consent should also include risks of EMI to the IPG, as the most severe risk includes damage requiring reimplantation of a new IPG. In addition, patient education is recommended on the need for frequent communication during the procedure regarding any abnormal sensation around the electrodes or IPG. Symptoms could include pain, paresthesia, or muscle activation.

Intraoperative Management

There is a risk of SCS devices being affected by EMI created during RFA. RFA uses radio waves to create current. This causes ions in the tissue to move, which then creates friction and the ultimate heating of tissues. Therefore, an electromagnetic field at the exposed tip of the needle is generated. The primary goal is to reduce the amount of EMI from the radiofrequency cannula to the IPG and stimulator leads. This can be done by reducing the distance between the radiofrequency cannula and the grounding pad, ensuring that it is less than the distance between the needle and IPG and/or leads, if possible. Specifically, Abbott (Abbott Laboratories, Chicago, IL, USA) has recommended that the IPG be placed in surgery mode and the bipolar setting utilized. Other medical device companies do not have these specific recommendations. In summary, bipolar ablation and keeping the grounding pad as close to the ablation site as possible will create the least amount of EMI.

Recommendations for intraoperative monitoring during the RFA procedure are primarily clinical. There have been reported cases of RFA causing interference with patients with implanted neuromodulating devices.[20] These were both with dorsal root ganglion stimulation using monopolar lumbar radiofrequency (motor activation) and cervical SCS with ablation of the cervical spine (pain and paresthesia in hands). In addition, it is recommended that patients have minimal sedation so there is adequate communication to the proceduralist. It is also advised that sensory and motor testing start at 0.1V with a slow increase and continuous patient communication. During RFA lesioning, the patient should be directed to report any abnormal sensations as discussed pre-procedurally. Although there are concerns regarding activation of the stimulator device during the procedure, the main concern is permanent loss of therapy secondary to EMI.

Postoperative Management

Following the procedure, the stimulator should be turned back on, or surgery mode should be turned off. Ideally, the functioning of the SCS device should be confirmed immediately after the procedure.

Recommendations: Application of guidelines and risk mitigation strategies in patients with SCS devices will likely improve patient safety and adverse events. Evidence is limited to case reports and additional high-quality studies are needed. Grade B, low level of certainty (Table 4).

Intrathecal Pumps

Background

Delivering intrathecal medication experimentally in humans dates to as early as 1898, with it gaining more widespread use clinically after 1979 for obstetric analgesia.[25,26] In 1981, an implantable intrathecal opioid delivery device was demonstrated for use in chronic pain secondary to malignancy.[27] Currently in the US, morphine sulfate and ziconotide are on-label for intrathecal infusions in the setting of chronic intractable pain. Baclofen is on-label for intrathecal infusion for the management of severe spasticity. Morphine, because of its low cost, support in literature, duration of action, and ease of use, remains the most common medication used in intraspinal analgesia globally; however, other off-label agents are frequently used in intraspinal therapy.[28] In 2007, the International Neuromodulation Society organized a group of experts

Table 4 SCS Manufacturer Recommendations*

Abbott[21] - no RFA specific recommendation	To avoid harming the patient or damaging the neurostimulation system, do not use monopolar electrosurgery devices on patients with implanted neurostimulation systems. Before using an electrosurgery device, place the device in Surgery Mode using the patient controller app or clinician programmer app. Confirm the neurostimulation system is functioning correctly after the procedure. During implant procedures, if electrosurgery devices must be used, take the following actions: • Use bipolar electrosurgery only. • Complete any electrosurgery procedures before connecting the leads or extensions to the neurostimulator. • Keep the current paths from the electrosurgery device as far from the neurostimulation system as possible. • Set the electrosurgery device to the lowest possible energy setting. • Confirm that the neurostimulation system is functioning correctly during the implant procedure and before closing the neurostimulator pocket.
Boston Scientific[22] - no RFA specific recommendation	If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, or high-output ultrasound: • Turn off stimulation at least 5 minutes before the procedure or application. • All equipment, including ground plates and paddles, must be used as far away from the IPG as possible. • Bipolar electrocautery is recommended. Do not use monopolar electrocautery. • Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the IPG. • Equipment should be set to the lowest energy setting clinically indicated. • Instruct patients to confirm IPG functionality following treatment by turning on the IPG and gradually increasing stimulation to the desired level.
Medtronic[23]	Radiofrequency ablation (RFA) is a surgical technique in which radiofrequency or microwave energy is used to destroy cells by creating heat. RFA used in patients with a neurostimulation system may result in, but is not limited to, overstimulation, unintended tissue damage, device damage, or device malfunction. If ablation cannot be avoided, consider the following precautions: • Avoid direct contact between the ablation catheter and the implanted system. • Position the indifferent electrode patch so that the electrical current pathway does not pass through or near the device and lead system.

(*Continued*)

Table 4 (Continued).

Nevro[24]	Safety has not been established for radiofrequency or microwave ablation in patients who have implanted leads as part of an SCS system. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage. If a patient is required to undergo electrocautery, lithotripsy, high-output ultrasound, radiation therapy, or ultrasonic scanning, the following precautions should be taken: • Turn the HFX iQ IPG off or disconnect the HFX Trial Stimulator from the implanted leads. Remove the HFX Trial Stimulator from the area. • All equipment, including ground plates and paddles, must be used as far away as possible from all implanted and external devices. • Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from all implanted and external devices. • Equipment should be set to the lowest energy setting clinically indicated. After the therapy or procedure, the patient should verify that the HFX iQ IPG or HFX Trial Stimulator is functioning properly by gradually increasing stimulation to the desired level. If a patient suspects that the HFX iQ IPG or HFX Trial Stimulator is not functioning properly after the use of these medical devices or procedures, the patient should contact their physician.

Notes: *Manufacturer guidelines included for reference, but list is not comprehensive and confirmation of device specific recommendations is recommended.

to evaluate evidence and create a Polyanalgesic Consensus Conference (PACC) to guide practice for intrathecal drug delivery which continues to update their guidelines.[29]

Components

An intrathecal pump consists of two components: a reservoir/pump and a catheter. The pump is anchored in the pump pocket using a suture loop on the outside of the pump, and the drug to be infused is stored in the pump reservoir. The two most common reservoir sizes are 20 mL and 40 mL.[30] The intrathecal catheter connects to the pump catheter port. After the drug is put in the reservoir, the drug moves from the pump reservoir, through the pump tubing, catheter port, catheter, and then to the infusion site. Typically, the manufacturer and model of pump are recorded on a radiopaque identifier visible on X-ray.

Location

Limited data exist regarding location or best placement level of the catheter tip. Guidelines recommend the catheter be centered in the spinal dermatome associated with the pain generator.[29] Thus, the location of catheter and pump will vary from patient to patient, although placing the pump in the lower quadrant of the abdomen is most common.[28]

Effect of EMI on Device

Safety has not been established for radiofrequency or microwave ablation patients who have an ITP.[30] Published data is limited to two case reports in which patients with an ITP underwent RFA; however, the authors did not specifically discuss concerns with the procedure in patients with an IT pump.[31,32] Strong sources of EMI can undesirably interact with the pump. This can include heating of the implanted pump that results in system damage and/or changes in pump operation or flow rate resulting in patient injury from tissue heating, reoccurrence of underlying symptoms, or significant or fatal drug underdose or overdose.[30]

Preoperative Evaluation and Management

Prior to RFA or any procedure that might interfere with an ITP, the provider should determine age of the device, the last time the pump was interrogated, current pump medication(s), and when the patient is due for refill or pump change.[33] Most pumps last 5–7 years and require a refill every 1–6 months, with this interval contingent on drug delivery rate and reservoir volume.[34] When known, it is recommended to review the manufacturer's guidelines for the specific device used. Consultation with the provider responsible for pump management is encouraged as this will help diminish possible complications. If unable to communicate prior to the procedure, it is important to have contact information for the

managing physician as well as a representative from the device's manufacturer company should any complications occur during the procedure.[28]

Intraoperative Management

If the anesthetic plan or post-procedural pain control involves opioids, vigilance must be taken to prevent inappropriate titration in patients receiving intrathecal opioids as administered opioids may induce overdose.[35] If the ITP is delivering baclofen, the addition of opioids for sedation or pain control may have an exaggerated response due to the synergistic nature of the drugs.[36] The patient's pre-procedural baseline status and hemodynamics should be documented as any significant variation may indicate overdose or withdrawal, which may represent a medical emergency.

Patient positioning as well as location of RFA needs to be considered as these variables can affect the pump or catheter. Most ITPs are implanted in the lower quadrant of the abdomen and are preferably positioned to avoid contact with the patient's waist or beltline as well as the pelvic girdle and ribs. For obese patients, the device may be implanted in the flank region to allow greater comfort while avoiding difficulties inherently found with a large abdominal pannus.[28] To decrease catheter damage or malfunction, avoid positions including twisting, excessive bending, or stretching that might obstruct, kink, dislodge, or damage the catheter.[37]

As previously discussed, safety is not established for patents with ITP undergoing RFA. If RFA is going to be performed in patients with an ITP, it is prudent to be cognizant of the catheter and pump location in relation to the ablation location while maintaining the greatest distant possible between the radiofrequency cannula and ITP components.

Postoperative Management

Given the various potential sources of device malfunction, it is essential to recognize the signs and symptoms of overdose or withdrawal. If device malfunction is questioned, a provider experienced with ITP management should be consulted and the ITP should be interrogated. There is no literature or guidelines which recommend the routine or prophylactic interrogation of ITP status post RFA where device malfunction is not suspected.

Recommendations: Application of guidelines and risk mitigation strategies in patients with ITP devices will likely improve patient safety and adverse events. Evidence is limited to case reports and additional, high-quality studies are needed. Grade B, low level of certainty (Table 5).

Table 5 DBS Manufacturer Recommendations*

Abbott[15]	Careful consideration should be used before using radiofrequency (RF) or microwave ablation in patients who have an implanted neurostimulation system since safety has not been established. Induced electrical currents may cause heating, especially at the lead electrode site, resulting in tissue damage
Boston Scientific[38] - no RFA specific recommendation	Electrocautery can transfer destructive current into the DBS Leads and/or Stimulator. See additional instructions below. Bipolar or monopolar electrocautery may be used. Electrocautery probes must be kept a minimum of 1 inch away from the implanted device. • Turn off stimulation at least five minutes before the procedure application. • All equipment, including probes, ground plates and paddles, must be used as far away from the Stimulator as possible and oriented such that energy is not directed through or across the Stimulator, Leads, or Lead Extensions. • Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the Stimulator. • Equipment should be set to the lowest energy setting clinically indicated. • Confirm the system is functioning properly following the procedure. Turn stimulation on and observe for the return of therapy to confirm functionality.
Medtronic[39]	Safety has not been established for radiofrequency or microwave ablation in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead-electrode site, resulting in tissue damage, including brain tissue

Notes: *Manufacturer guidelines included for reference, but list is not comprehensive and confirmation of device specific recommendations is recommended.

Deep Brain Stimulators (DBS)

Background

Stimulation of cortical structures dates back as far as the 1930s. Initially employed using modified pacemakers, deep brain stimulation was developed to treat chronic pain and later applied to tremor disorders. The mechanisms underpinning the therapeutic effects of DBS remain unknown; however, neurophysiological, neurochemical, neurovascular, neurogenic, and neuro-oscillations all play a role. Therapy can be individualized to each patient using different combinations of amplitude, frequency, pulse width, and electrode configuration.[40]

Indications

DBS has been approved to treat a variety of conditions including Parkinson's disease, dystonia, essential tremors, chronic pain, intractable focal epilepsy, and certain neuropsychiatric conditions such as Tourette's syndrome, depression, or obsessive-compulsive disorder. Several experimental indications are being tested such as obesity, PTSD, drug abuse, and addiction.[40]

Components

DBS technology involves placement of one or two leads with four (4CH) or eight (8CH) channel contacts into a specific and predetermined brain target. The 4CH leads have four cylindrical electrodes that can deliver stimulation in all directions. The 8CH lead has two cylindrical electrodes, similar to the 4CH lead, and has two central contacts consisting of three segments that can be activated independently to concentrate stimulation in one direction. This theoretically reduces the current needed to produce meaningful therapeutic effects.[41] The electrodes are typically placed within the basal ganglia structures, specifically the subthalamic nucleus. The leads are connected to an insulated extension wire that is tunneled to an implanted pulse generator. The IPG is commonly implanted in the infraclavicular region, though location may vary based on surgeon and patient preference. IPGs are either single cell or rechargeable. Newer models allow for recording and sensing brain signals while delivering stimulation.

Effect of EMI on Device

EMI from RFA treatments may be transmitted to implanted DBS devices. Delivery of excess electrical energy through the leads can cause neurolytic changes resulting in severe injury or death.[42] Patients may describe "jolting" or "shocking" in cases of increased stimulation. EMI can cause system damage or reset requiring reprogramming or surgical replacement.

Preoperative Evaluation and Management

DBS devices have become more complex in recent years, offering multiple program settings and therapies. Prior to proceeding with the RFA procedure, information should be obtained regarding the system such as indication for implantation, device manufacturer, and IPG location.[43] Another important piece of information to delineate is severity of symptoms should the device be turned off, as this may preclude patients from undergoing the procedure from a safety perspective. It is also important to have detailed discussion with patients outlining risks to device and damage resulting in the need for IPG/lead revision.

Intraoperative Management

Intraoperatively, risk to the DBS system is present during RFA. This risk is present during the activation of the radio waves, resulting in a current to heat and ablate the targeted nerve. The risk in this scenario is primarily through inappropriate activation of the stimulator as well as generating EMI that damages the IPG, rendering the entire system nonfunctional. First, the system should be turned off or programmed to surgery mode prior to performing the procedure to minimize EMI. Second, the grounding pad should be placed as near as possible to the RFA needle to minimize the dispersion of electrical currents. Bipolar RFA is also a preferable treatment option, if available.[43]

Postoperative Management

Immediately after the ablative procedure, the DBS system should be powered on and returned to prior settings. It is also recommended that the device be interrogated in the immediate postoperative period by either a DBS device representative or a physician/advanced practice provider with experience involving the device.[43]

Recommendations: Application of guidelines and risk mitigation strategies in patients with DBS devices will likely improve patient safety and adverse events. Evidence is limited to case reports and additional, high-quality studies are needed. Grade B, low level of certainty.

Conclusions

Considering an aging population, the dichotomy of both osteoarthritic disease and cardiovascular or central nervous system disease in the same patient is strikingly likely. Considering this, the need for both RFA ablation and implantable cardiac, neuro, or other devices will become more common in all settings. Adherence and attention to this guidance will improve safety and efficacy, thus leading to improved care.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

Dr Timothy Deer reports grants, personal fees from Abbott, during the conduct of the study; personal fees, Consultant, Stock Options, Research from Vertos, personal fees, Consultant, Stock Options from SpineThera, personal fees, Consultant, Stock Options, Research from Saluda, personal fees, Consultant, Stock Options from Nalu, Consultant, Stock Options from Cornerloc, personal fees, Consultant, Stock Options from Ethos, personal fees, Consultant, Stock Options, Research from SPR Therapeutics, personal fees from Medtronic, personal fees, consultant, Research from Boston Scientific, personal fees, Consultant, Stock Options, Research from PainTeq, personal fees from Tissue Tech, personal fees, Consultant, Stock Options from Spinal Simplicity, personal fees from Biotronik, Research from Mainstay, Research from Avanos, outside the submitted work; In addition, Dr Timothy Deer has a patent Abbott pending to pending The authors do not have any financial disclosures or other conflicts of interest to report.

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